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A COMPREHENSIVE REVIEW ON REGULATORY REQUIREMENTS OF PHARMACEUTICAL DRUG PRODUCTS IN CIS AND GCC COUNTRIES

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ABSTRACT: India may have a potential in the Commonwealth of Independent States (CIS) region. Pharmaceuticals are difficult to register with the CIS region's regulating organisation because of the turmoil among these countries. The CIS includes Russia, Ukraine, Kyrgyzstan, Uzbekistan, Tajikistan, Kazakhstan, Turkmenistan, Azerbaijan, Armenia, Belarus, Moldova, and Georgia. These call for various regulatory standards for drug registration. Based on the FDA's recommendations, it will be problematic to have various policies in the same area- activity of exporters and producers; registration of the same product in various nations; work of manufacturers and exporters. The same documents cannot be used to implement CIS due to the lack of regulatory harmonisation. Manufacturers and exporters must submit various country-specific documents to reach these markets since these nations adhere to a country-specific document format. Both Ukraine and Kazakhstan have enacted stringent regulations and are awaiting United States Food and Drug Administration (USFDA) - level document certification. The Gulf Cooperation Council (GCC) is regarded as a "growing industry both in terms of trade agreements and drug exportation." During 2008–2009 in certain cases, the GCC's healthcare sector will indeed be dominated by patented medications. This article's purpose is to assess existing regulatory frameworks of the GCC member countries (Bahrain, Oman, Kuwait, Saudi Arabia, Qatar, and the United Arab Emirates (UAE) to ascertain a coordinated approach. In addition to the GCC Team, the GCC Commission for Drug Monitoring was founded and put into action by purchasing medications as well as pharmaceuticals on its own efforts.

INTRODUCTION: The field of regulatory affairs (RA) serves as a link between the global pharmaceutical sector and regulators. One of the responsibilities of these authorities or bodies is to stay up to date with changes in the regulations governing pharmaceutical drug research, distribution, and marketing [1].

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It is formed in response to the government's desire to safeguard controlling the effectiveness and safety of pharmaceuticals, veterinary medications, and medical supplies, pesticides, agricultural chemicals, cosmetics, and other products.

Companies that are in charge of these items' research, manufacture, testing, and sale furthermore wish to guarantee the effectiveness and safety of their products for the overall welfare of the public [2]. Interpretation, application, and communication within and outside of the organisations are crucial to the effectiveness of the regulatory process. Drug Regulatory affairs is a brand-new career that was developed by governments to safeguard global

health by policing the efficacy and safety of products across a range of categories including prescription drugs, veterinary drug treatments, medical devices, insecticides, agrochemicals, cosmetics, and complementary and alternative medicines. The businesses that produce and market these goods should make sure to offer high-quality goods to the general people for their health and welfare. Nowadays, most agencies have skilled regulatory affairs divisions. The only internal department that experiences the least influence from acquisitions, mergers, and economic downturns is the regulatory affairs department, which is always innovating and growing [3].

History Overview of Pharmaceutical Industries and Regulatory Affairs: In the 1950s, numerous catastrophes, including those involving the sulfanilamide elixir, vaccines, and thalidomide, led to a substantial increase of the rules that control the efficacy, safety, and quality of pharmaceutical products. Additionally, this has resulted in stricter guidelines for Marketing Authorization (MA) and Good Manufacturing Practices (GMPs). In order to understand the chronological development of the current time of the pharmaceutical sector and regulatory framework, we will quickly review the historical evolution of policies in the USA, Europe, and India. Keep an eye on what happens in India, Europe, and the USA [3].

CIS Countries: In December 1991, CIS was founded. Federal participants proclaimed cooperation based on equal sovereign rights in the declaration that was adopted. There are currently 13 countries that make up the CIS. The Single Financial Space was established by the CIS leaders based on the free movement of people, capital, labour, products, and activities (1993). The procedure of the control of enterprise wide being incorporated into a business agreement was accepted. The agreement provides advantageous guidelines for the development of direct manufacturing relationships. In order to establish the necessary coordinating organisations (Belarus and Russia) and promote future integration, the Union of the Sovereign Republic was launched in 1995.

Four countries signed the accord (Russia, Kyrgyzstan, Kazakhstan, and Belarus). Tajikistan formally joined the CIS states in 1999, following the formation of the Council of Four nations. The heads of five countries – Tajikistan, Russia, Kyrgyzstan, Kazakhstan, and Belarus – sanctioned the agreement on the foundation of the Eurasian Economic Community (2000). Armenia, Moldova, and Ukraine were all participants in the Eurasian Economic Union. Uzbekistan announced its membership in the group in 2005. The four nations (Belarus, Russia, Kazakhstan, and Ukraine) agreed to establish the Common Economic Space (CES) in 2003, as stated in **Table 1**. The coordinating authorities of the various nations bring them together to form the Commonwealth of Independent Nations (executive, legislative, and CIS industrial cooperation bodies) [4].

TABLE 1: LIST OF REGULATORY BODIES & RESPONSIBILITIES FOR CIS COUNTRIES

S. no.	Country Name	Regulatory Bodies	Responsibilities
1	Armenia	Pharmaceutical and medical advancements research institute	Medications and veterinary drugs evaluated by experts and submitted for registration in RA
2	Azerbaijan	Centre for Experimental Expertise	The Ministry of Health (MOH) is in charge of controlling drug marketing and advertising
3	Belarus	MOH	Issuing permits for import and export of registered pharmaceutical medicinal products
4	Georgia	Department for Drugs and Narcotics in Georgia	Enforces Georgia's rules and regulations to safeguard the population' healthcare, economy, and protection
5	Kazakhstan	National Center for Medical Equipment, Devices, and Drug Expertise	Establishing national strategies for quality surveillance of health care and creating the legal framework for such oversight
6	Kyrgyzstan	Ministry of Medical Devices and Drug Distribution	Supplies Kyrgyzstan's inhabitants with high-quality, secure, and safe medications
7	Moldova	Medicines and Medical Devices Agency of the Republic of Moldova	Provides marketing approval for pharmaceuticals
8	Russia	Federal Health care Surveillance Service	Performs legal rules of medication prices that belong to the government-approved list of essential medications

9	Tajikistan	MOH	In Tajikistan, the Ministry of Health oversees and controls the healthcare system
10	Turkmenistan	MOH of Turkmenistan's Republic	The MOH is in charge of registering pharmaceuticals
11	Ukraine	MOH	certification and pharmaceutical quality management control
12	Uzbekistan	The Republic of Uzbekistan's Ministry of Public Health	The MOH establishes the rules and regulations for pharmaceuticals and medical equipment

The Scientific Center of Drug and Medical Technology Expertise's role in Armenia is to carry out the country's drug policy and to guarantee the security, effectiveness, and calibre of the country's pharmaceuticals. Legal measures are in place in Azerbaijan to control the promotion and advertising of prescription pharmaceuticals. The MOH is in charge of changing how medications are advertised and promoted.

Granting permissions to import and export recognized pharmaceutical and medical goods is one of MOH's primary responsibilities in Belarus, along with inspecting products for state registration or reregistration. The National Regulatory Authority in Georgia enforces Georgian rules and regulations to safeguard the public welfare, healthcare, and protection in the certification and distribution of manufactured or combined medications, and only to licensed individuals.

The MOH is accountable for emerging new regulatory frameworks on quality management and the legal structure for quality assurance of hospital services in Kazakhstan, in addition to abiding to the rules for granting medical practice authorization. Establishing a control and oversight system to afford the general population with a variety of secure, high-quality, and efficient drugs, medical devices, pharmaceuticals, and beauty products is the main objective of the regulating agency in Kyrgyzstan.

The national medical regulatory body in Moldova is responsible for the market authorization, market oversight, quality assurance during production, and clinical trial oversight of pharmaceutical products.

The Russian government abides by the regulatory oversight of the prices of medications recognized on the government-approved list of innovative pharmaceutical goods. The Republic of Tajikistan's Ministry of Health oversees and supports the country's public health system in addition to controlling the health sector.

State registration facilities for pharmaceuticals are maintained by The Ministry of Health and the Medical Technology of Turkmenistan. The professional organization is accountable for registering drugs.

The company has finished its examination of the pharmaceutical product paperwork. In Ukraine, a specialist body called the State Expertise Centre was in charge of preclinical and post-clinical studies, drug products licensing and quality standards, monitoring drug-related adverse outcomes, and approving the import and application of unregulated pharmaceutical drugs. The MOH develops the rules and regulations for pharmaceuticals and medical equipment in Uzbekistan. It handles state registration, medical device quality control, and pharmaceutical activity licensing [5-7].

CTD (Common Technical Document) DOSSIER: The human medical product method for obtaining marketing approval must include a CTD. The MOH, FDA, or equivalent entity must receive the regional format or CTD dossier together with additional necessary technical documentation and regulatory manufacture approvals or another appropriate authority.

Pharmaceutical experts can give assistance for drafting comprehensive technical documents for product registration in various nations throughout the world as given in **Table 2** [8]. There are 5 modules in the CTD Dossier Compilation Format.

Module 1: Administrative and Prescribing information.

Module 2: CTD Overview and Summary of pharmaceuticals.

Module 3: Quality Overview (Pharmaceutical documentation).

Module 4: Non-Clinical Research Reports.

Module 5: Clinical Research Reports.

TABLE 2: STRUCTURE OF CTD

ICH-CTD	Overview	Observations
Module 1: Administrative and prescribing information	It contains records particular to each nation. Administrative documentation, such as submitting registration forms and permitted reports, good manufacturing practises certification, etc., make up the majority of it	Required for both generic and novel medications
Module 2: CTD Overview and summary of pharmaceuticals	It provides an overview of the data contained in the dossier's Modules 3 (Quality Data), 4 (Nonclinical Statistics), and 5 (Clinical Statistics). The analyst receives an overview of all submissions made across the implemented system in this module	Need for generics and new medications. Only a description of a Factor responsible is necessary for identical items
Module 3: Quality Overview	The standard for scientific information, pharmaceutical industries information, and genetic analysis of both various drugs and finished products are all covered in this module	Entailed for both generic and novel medications
Module 4: Non-Clinical Research Reports	Information on the pharmacological, physiological, and chemical analysis of the pharmaceuticals are given in this module	Not for similar medicinal products
Module 5: Clinical Research Reports	A careful assessment of patient research and pertinent studies is provided in this session	A pharmacokinetic and pharmacodynamic study is the only exception for similar medicines

In the semi-regulated and regulatory sectors, such as those found in the CIS, the USA, Australia, the EU, Japan, *etc*., the CTD format dossier is frequently adopted [8-9].

Gulf Cooperation Council (GCC) Countries: When it comes to pharmaceuticals exports and cross-border industry, the GCC region is regarded as a "Entrepreneurial Firm." Considering the local legal standards can be useful when exporting pharmaceuticals. A few events in the years 2008–2009, such as the crisis or downturn inside the fully advanced and governed markets of the EU and US, increased the desire for substitute company locations. The importation of high-quality similar medicines is encouraged by GCC rules, which may be excellent news for Indian pharmaceutical companies. The organization of Petroleum Exporting Countries Council, also known as the Alliance again for Arab States of the Gulf, was established since May 25th, 1981. The Kingdom of Saudi Arabia, UAE, Sultanate of Oman, State of Kuwait, State of Bahrain, and State of Qatar seem to be the original members [10]. The Board has significantly harmonised laws ever since founding. Its efforts led to the creation and functioning of the GCC Commission for Pharmaceuticals Monitoring as well as the GCC Group Purchasing of medications and medical equipment, among other things. Additionally, the certification of production facilities and the consolidated process united the nation's medication certification. The study's main concern is the.

- ❖ Organizations engaged.
- ❖ Description of the procedure including key timeframes.
- ❖ Standards again for Centralized Process.

GCC Countries' Geographical Composition: The six Gulf states' racial and ethnic composition According to **Table 3**, the Gulf region, which is made up of the 6 GCC member states (Bahrain, Oman, Kuwait, Qatar, Saudi Arabia, and UAE), has a territory of 2,572,954 Km^2 [11]. Its demographic totals 47.5 million, with such an average lifespan of 29.1 years and an average lifespan of 75.4 years. Saudi Arabia is the nation's most populous nation with the fastest growing economy. It was discovered that Qatar has the greatest average lifespan and also the greatest infant mortality rate. Bahrain, the tiniest of the nations, has the second-highest average lifespan and the third-highest Revenue among the nations with the least populated and greatest Economy. The need for pharmaceuticals in the area might well be impacted by the racial composition of the GCC states. While the number of individuals between the ages of 25 and 64 achieved a median of 56.8% in 2014, the fraction of individuals over the age of 65 attained a mean of 2.1%. The GCC community is primarily made up of youngsters, as per Alpen Vision 2013. Although infant mortality rates are declining, the average lifespan is gradually rising, [12] which is predicted to cause the corresponding figure to rise. Therefore, signifies that over the coming generations, the demographic of the Gulf nations

would probably grow significantly as even more individuals attain the age of 60. This should raise medical costs while elderly adults often have higher hospital services than youngsters. According to the number of old individuals in the GCC region who need hospital services is rising as a result of rises in life span over the previous 25 years. According to the Alpen Financial Survey 2013, the population is predicted to increase at a compound annual growth rate (CAGR) of 6.1% from 2012 to 2050 [13].

TABLE 3: GCC COUNTRIES GEOGRAPHICAL COMPOSITION

Country	Area/km^2	Population/ million (2014)	Median age (years)	Life expectancy at birth (years)	% Population age (25–64 years)	% Population age over 65	GDP ($) in billion	GDP per capita ($)
Bahrain	760	1.3	31.6	75.2	58.9	2.6	23.0	18,334
Kuwait	17,818	3.3	28.9	74.7	54.5	2.1	176.6	56,514
Oman	309,500	3.3	24.9	73.3	45.9	3.2	71.8	23,731
Qatar	11,586	2.1	32.6	78.3	70.8	0.8	173.0	90,523
Saudi Arabia	2,149,690	28.3	26.4	74.1	48.6	3.1	576.8	20,777
UAE	83,600	9.2	30.3	76.7	62.1	1	360.2	40,363
Total	2,572,954	47.5	–	–	–		–	–
Mean	–	–	29.1	75.3	56.8	2.1	230.4	41,707

In addition, the GCC nations' rising industrialization and per capita spending, combined with the region's warm country, have encouraged unhealthy lives and the intake of imbalanced meals, which has resulted in a significant prevalence of illnesses like overweight, diabetes, and cardiovascular events [14]. Market forces for medical products made domestically have been influenced by the high levels of wealth of the regional individuals as a whole. Consumers show a significant preference for private labels, that are still in the growing market despite patent expiration and the accessibility of less expensive counterfeit alternatives (Alpen capital 2013).

Opportunities in the GCC Market:

- GCC countries - 80% demand of pharmaceuticals through import.
- More than one million annual increase of population - Great potential for healthcare sector.
- Largest trading partner after US - 6.8 USD billion business annually.
- Indian export to GCC countries- 119.25 USD billion (2002-03).
- Less custom duty on pharmaceuticals- duty-free (Saudi Arabia & UAE) and 4-5% by all the remaining GCC members.
- Economic development boards (EDB), joint ventures and economic liberalization by GCC countries - Opportunities for Indian investors [15].

Requirements: The registration procedures for pharmaceutical drugs in various CIS nations, including Regulators were concerned about Belarus, Kazakhstan, Armenia, Ukraine, Uzbekistan, and Kazakhstan (pharmaceutical company involves in export to CIS countries). Specific recommendations, rules, guidelines, and governing bodies were used to compile the data. Additionally, the available articles evaluate the results.

CIS Countries with its Corresponding Authorization Process and Regulatory Conditions (Russia, Ukraine, Uzbekistan, Armenia):

Russia: To plan and carry out the legislation, the regulatory agency works directly with the health-related authorities in the CIS countries. Each CIS country has registering rules and requirements. The global authorization of drug products usually requires 24 months to accomplish. The documents have been written in Russian and therefore were formatted in accordance to Russian laws. The prescribed work of bioequivalence studies was completed by research institutions with accreditation in Russia. Original and generic products go through the same registration process.

Generic items were exempt from several registration requirements while original products must adhere to all of them. For instance, clinical studies for a novel product were required in Russia. Bioequivalence tests can be conducted outside of Russia for generic medications as well [16].

Registration-Required Documents:

Registration Form with Supporting Documentation: The manufactured product's binomial nomenclature, registered trademark (in Latin), and worldwide non-proprietary identifier, as well as any additional information (INN).

- A list of excipients as well as a list of the dosages and indications for each active pharmaceutical component.
- Storage conditions, Shelf life, Drug information, Packaging.
- A manufacturer-issued legal authority (Authentic Notarization with Expunction) given to a business with permission to complete the registration process [17].

Powers and Certified Documents Include:

- Free Selling Certificate, certified document (FSC).
- A drug product's licence.
- Good manufacturing certification.
- A certified true copy of the country-specific license application for the supplier.
- Regulatory Documentation, often known as Normative Technical Document (NTD).
- These include documentation that list the requirements, specifications, or qualities for particular actions or outcomes.
- A duplicate Certification of Analysis (COA) of the drug component and the feedstock, sealed and signed by the industrial chemist.
- A duplicate of the company's registered and approved copyright document.
- Details about the product's licensing in the nation of the maker and some other nations.
- The CTD formatted report.
- System representing specimens, active pharmaceutical tests including, if necessary for evaluation, High performance liquid chromatography (HPLC) chambers.
- Packing information [18].

The Reliability of Enrolment: The licensing was good for five years.

Conditions for Sustainability: Investigations of lengthy sustainability were needed because Russia has been in temperature zone II were undertaken at temperatures of 25°C to 2°C and 60% to 5% relative humidity, whereas studies of short-term stability were conducted at temperatures of 40°C to 2°C and 75% to 5% RH [19].

Authorization Costs and Schedule: The certification process takes 210 days, so each product produced by an overseas manufacturer must pay a cost of $12,000 during that time.

Russian Drug Regulatory Procedure: The regulating agency in Russia was called as Federal Agency for Monitoring in Health, has a section of health control called Roszdravnadzor that registers pharmaceutical products. The item was shipped to Russia after being registered with the Russian Ministry of Health. Russia has a unique regulatory system that was incompatible with the way pharmaceutical items were regulated in the US or EU.

Three steps make up the registration procedure. The applicant was required to gather all required paperwork for the file at the beginning of the process. The Federal State Unitary (FSU) then receives these documents after they have been translated into Russian. In order for them to evaluate quality, efficiency, and safety, the file was delivered to the strategic and analytical at the Centre for Product Quality Management and Centre for Preclinical and Medical Research in the second phase. It was the hardest and toughest step of the entire process. The penultimate step entails finishing this assessment and delivering the file to Rosadravnadzor so that a product registration certificate can be issued.

The length of the registration process will vary depending on how well the regulatory expert was organised and performing. Additionally, if additional clinical studies, quality assurance measures, or requests for additional clinical evidence from regulatory agencies were made, the licensing deadline would be postponed. But typically, the production of a Registry Certificate took approximately 18 months, with Stage I taking around two months, Stage II about twelve months, and Stage III about four months [20].

Ukraine: All pharmaceutical medications in Ukraine were usable upon state registration. Data upon that registrant, producer, including specifics regarding the pharmaceuticals were required for state registration of pharmaceutical items (Methods of medication dose, a summary of its constituent parts and active substances, both quantitative and qualitative formulations, and preservation guidelines, *etc*). The MOH of Ukraine's state expert centre oversees pharmaceutical product registration and quality monitoring.

Certificates Needed:
The Essential Records were Necessary:

- A notarized document of the Statistical Process Control (SPC) and an authority to act from the company's country were also required.
- A duplicate of the company's drug manufacturing permit that confirms towards the company's right to create prescription medications.
- The countries in which the product was licensed; Normalized Technological Documentation (NTDs).
- A certification stating that the European Pharmacopoeia (Ph. Eur.) standard was appropriate.
- Further, reference tests and free samples were needed, together with a documentation for certification in the CTD (Common Technical Documents) format.
- All pharmaceutical products, regardless of whether they're label or common, should include a complete documentation of pre-clinical and clinical study data. Reference tests and free samples were also necessary [21].

Persistence of Registration: The registration was good for five years.

Stability Prerequisite: Although Ukraine was in climate zone II, research of long-term durability should be done at temperatures of (25°C, 2°C) and (60%) relative humidity (RH), while studies of short-term stability should be done at temperatures of (40°C, 2°C) and (75%, RH).

Registration time: Generally, 210 days [22].

Fees Needed: This was EUR 100 for drug dosage forms; each additional dose and packet of the medical product costs EUR 10.

Ukraine Registration Process: The candidate provides the State Drug Inspector with the registration application and the required supporting documentation, which attests to the drug products' efficacy and safety. The State Drug Inspector will analyse the supplied documentation in no more than 90 days. In order to review the appropriate materials, evaluate the medications, and refer the application appropriately, the examination will work with the State Drug Inspector expert institutions.

From a listing of descriptions of specialized centres that the Drug Control Inspector has compiled and updated, the applicant chooses the institution. The report that was given either straight to the applicant or to the Drug Control Inspector must include the results of the test (conducted by the institutional experts). The State Drug Inspector will permit examining of the drug goods grounded on the conclusions of the expert institutes. Notably, the schedule of such exams won't change the duration of the time. during which the specialist examination will be administered. When deciding whether to register or reject a drug product for state registration, the Ministry of Health bases its decision on expert testing findings and the recommended body's approval. The applicant was informed by the state's drug inspector in ten days. According to the Ukrainian Ministry of Health's regulations, pharmaceutical items must be listed in the official documents of the State Drug Inspector.

A drug's state application for registration items was obtained by applicants. If any additional medical product modification was required, this must be submitted with the certificate. The registration certificate has a maximum 5-year shelf life. Only once the drug product has been reregistered following the end of the trade time in Ukraine were sales and uses of the drug product permitted [23].

Renewal of Registration: Every five years, a drug product's registration must be revised. A renewal required a submission, re-registration fees, context - based (competence), and responses to any deficiencies until the goods was approved were required documents for the renewal of registration. Non-clinical sample studies were not essential at the time of registration renewal.

Modern rules and standards must be followed when renewing registration. The renewal process will involve revisions to the registration documentation. Separate applications should be included for each new alteration and required rationale [24].

Uzbekistan: The Uzbekistan health ministry was in charge of application for registration of prescription drugs, medical instruments, and machinery. A five-year registration certificate was provided based on the application for registration of pharmaceuticals, medical devices, and hospital instruments.

Medications, surgical instruments, and instruments, as well as medical inventions, may all medical settings up until the registration certificate's validity expires, provided that they were manufactured within the registration certificate's legal production window and before that date [25].

Registration-Required Documents: The application form must be accompanied by an authority of notary, the manufacturer's business licence, a judicial manuscript of the company's licence of drug sales attesting to the company's authorization to generate prescription medicines, a certified copy of GMPs, overall pharmaceuticals details, a manuscript of the applicant's as well as the company's written statement of contract, and a Certificate of Certification of Compliance (COPP). The registration of the dossier was completed in a four-part regional structure and includes regulatory, biochemical, medical, bio-pharmacological, and medical evidence. Duplicate specimens of the drug products and the specified amount must be used during testing [26].

Persistence of Registration: The registration was good for five years.

Stability Prerequisite: Due to Uzbekistan's climate zone II designation, studies of hard durability were conducted under conditions of heat (25°C 2°C) and moisture (60% 5% RH), whereas studies of short-term stability should be done under circumstances of temperature (40°C 2°C) & moisture (75% 5% RH).

Period for Registration: For 6 to 8 months.

Fees Needed: Application costs were 175 euros.

Uzbekistan Application Process:

- The applicant must provide two documents to the director of pharmaceuticals and medical product testing for the licensing of pharmaceutical products in Uzbekistan.
- The candidate sends in supporting paperwork and tests of the medication they intend to register.
- Following the submission of the paperwork and evidence, an agreement was reached between the submitting company and the government office for competence and standardisation in pharmaceuticals.
- The Department submits materials to the numerous specialist bodies (Medicinal Council board, Drug Enforcement Council board, Biosynthetic pathway Council board, and professional Council of specialists).
- After reviewing materials and performing any standard actions on documentation, the Director of Product Testing for Pharmaceuticals and Medical Products declares a drug substances license.
- The readily Determine Certificate will be provided by the public registry within ten days of receiving confirmation from the board of members [27].

Armenia: The Ministry of the Armenian People's Republic has implemented the licensing of drugs.

The Regulatory National Authority receives the registration solicitations. The documentation was offered in English, Russian, or Armenian. Only after registration were drugs allowed for import, practise, and use in Armenia.

Documents Required for Registration: Summary of Product Characteristics (SmPC), a certificate for a true copy of the pharmaceutical product, also known as a Certificate of Pharmaceutical Product (CPP), a drug registration manual, a design of the therapeutic agent, and a registration number of the label were all necessary documents for registration. For renewed registration, pharmaceuticals, packages, and Periodic Safety Update Reports (PSUR) were required [28].

Persistence of Registration: The registration was good for five years.

Stability Prerequisite: In light of the fact that Armenia was in climate zone II, research on long-term stability was done at temperatures of 25°C to 2°C and humidity levels of 60 percent to 5 percent relative humidity, while studies of short-term stability should be conducted at temperatures of 40°C to 2°C and humidity levels of 75 percent to 5 percent.

Registration Costs and Times: For 180-day registration period, registration fees range from 900 (thousands Armenian dram) for the generic drug's initial dosage form and dosage strength to 450 (thousands Armenian dram) for further pharmaceutical forms and dosage strengths to 450 (thousands Armenian dram) for new signs (thousands Armenian dram) [29].

Registration process for Armenia: The steps involved in registering a drug product in Armenia include submitting registration dossier applications, drug product samples, the full collection of charges, the early assessment (equipment surveillance), the choices taken during the early assessment, and the receipt of charges for expert labour. Reviewing certain records (purity, security, and effectiveness inspection), hazard control, and evaluating the production system were further processes. The issue of specialised expertise has been resolved. The medicine product's safety and quality have been approved by the laboratory examination. The Pharmacological Board receives the exam results for review. The Armenian regulatory body then issues the registration certificate. The producing nation's GMP certificate was granted during the registration process; an examination of the manufacturing facility was not necessary [29-30].

GCC Countries:

Drug Registration:

- ❖ Centralized registration procedure.
- ❖ Decentralized registration procedure.

Officials participating in the GCC's Centralized Procedure: Gulf Healthcare Council (GHC) The formed Healthcare Directors Committee oversaw member nation collaboration prior to the creation of the full GCC organization.

Medical resources, top-notch technology, and medical applications with a track record of reliability, security, and effectiveness must all be purchased by the GHC. Through to the centralised process, all commodities need receive approval [31].

The executive office of Gulf Central Committee for Drug Registration (GCC-DR) accepts enrolment documents with verification that all licensing prerequisites have been met and then upon properly completing the forms:

- ➢ The attached herewith for pharmaceutical firms.
- ➢ A information sheet for medicinal active compounds or preparations.

1. Two Specimens must be sent to every nation with the licensing document, together including 8 comprehensive documents for every specific chemical, 17 tests, and 17 test results must be presented to the executive office [32].
2. Each nation was required to carefully review the enrolment documents that have been sent to it before returning them together with a suggestion to the commission. **Fig. 1** illustrates the process.
3. The business must offer laboratories for such examination of standardized products, procedures, *etc*.

4. The executive office sends chemicals substance sampling collections to term referring laboratories for testing.

5. The last verification and documents were concluded on a country-by-country basis in compliance with its specified and authorized regulations just after centralized approval of the establishment of a corporation and/ or chemical entity.

6. The register document was issued by the executive office [33].

7. The businesses have the option to file complaints with the executive office following 2 months after receiving notice that they have been registered by that of the GCC-DR.

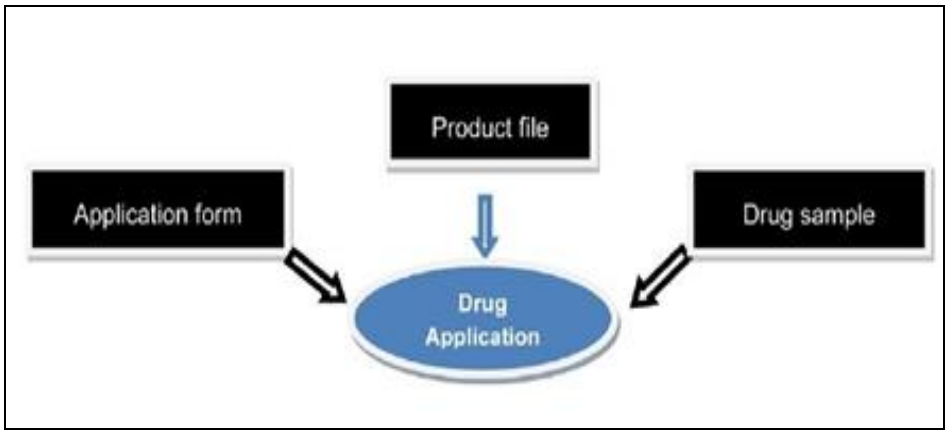

FIG. 1: ELEMENTS OF THE DOSSIER

Costs for Registering Drugs:
Business Register:

- SR. 5000, which represents the 50% cost for looking through the industry's record.
- SR. 5000, whereby, with official consent and authorization of its registrations, will constitute 50% of the remaining amount.

Register of Products:

- SR. 3000, which really was 50% of such registering charge in exchange for reviewing the industry's documentation.
- SR. 3000, that, following official authorization and consent for its registrations, equal to the probability 50% of remaining fee [34].

The Decentralized Enrollment Process: GCC key country registering laws whereas the GCC nations have a centralised and largely uniform procedure for registering drugs, certain major nations, like Saudi Arabia and the UAE, have unique guidelines. Several nations had built legislative framework that were upheld. These four GCC nation's (Saudi Arabia, Bahrain, Kuwait and UAE) multi-source major product licensing regulations will be extensively discussed in this research [35].

Saudi Arabia: The primary Saudi Arabian regulating organisation for drugs was the Saudi Food and Drug Authority (SFDA). The SFDA supports uploading of pharmaceutical documentation (eCTD). Up until May 20, 2010, the SFDA had authorized and over 6177 medications of various strengths as well as compositions. The following were the conditions and steps for marketing authorization [36]:

Approval of Drugs:
Online Registration Submission: A registration number was provided to the registrant after the application has been received to allow for easier with SFDA easier.

To submit the application, the candidate must schedule a meeting with SFDA headquarters. One to twelve weeks in ahead was allowed for scheduling the earlier consultation. One week prior to the medical meeting, the candidate may postpone [37]. Three days prior to the meeting, an automated notification will be issued. The SFDA's system was to regulate timeframe was displayed in following:

Timelines for Achieving Goals:
Procedure and Goal Achievement Period (Days):

- Generic pharmaceutical marketing authorisation (MA) applications - 165 days
- Proposal for a marketing approval (MA) for a unique chemical element (NCE) – 290 days
- Biopharmaceuticals marketing authorisation (MA) request – 290 day [38].

Format: CTD format was used. suggested by eCTD. Modules 2 through 5: in ICH CTD format. Module 1: localized specifications [39].

- Request form.
- The elements list.
- A request form.
- Packaging includes a description of the company's products (SmPC), a product specifications booklet (PIL), including labelling, all in the standards prescribed in the WHO standard.
- Details on the professionals who participate in clinical and nonclinical investigations.
- Risk analysis for the ecosystem.
- Regulatory affairs.
- Pharmaceuticals certification (COPP).
- Valuations..
- Answers to the SFDA's inquiries (in any).

Demonstration:

- Hard copies were packed in laminated sheets (A4 size, 2 laminated sheets). A maximum of 300 pages per folder.
- DVD or CD-ROM as a word document. One physical edition, two digital files. (Only modules 1, 2, and 3 for New Chemical Entities (NCEs), biopharmaceuticals, and biologic drugs were available in paper form). Content shouldn't be accessible; it must be autostartable; must be "adware" and unlocked without a login; Arabian or English as the region [40].

Approvals: Verified by both the Saudi Arabian consulate as well as the state health department of the nation of origin. Those credentials were necessary:

- The COPP/free trade license.
- Certificates of Analysis (CoA).
- A statement saying no pork.
- Retail value.

Bahrain: Bahrain's medicinal registration requirements were largely identical to those in the remaining GCC nations. The Department of Health in Bahrain requests all sorts of content, although in contrast to certain other GCC nations, Bahrain places more emphasis just on specifics of the official page and various economic operations, such as the corporation's most group in partnership [41].

Background Knowledge:

- ✓ Case features.
- ✓ How many production facilities the firm owns.
- ✓ Description for every location.
- ✓ Business and Economical ties within all websites.
- ✓ Production permit from the home nation, with dates (Certificate of Origin - COO).
- ✓ Identity and phone numbers for the application.
- ✓ GMP document was issued by the home nation.
- ✓ Amount of jobs in each department and information about respective qualifications.
- ✓ Visual layout and project's information for the company workflow.
- ✓ A listing among all goods produced by the business, any suppliers and manufacturers, and any additional parties with marketing rights (Marketing Authorization Holder - MAH).

- ✓ Connection to MAHs.
- ✓ Any earlier examination by the GCC or Arab health agencies.

Officials in the Ministry of Health with details: Any purchase, merger, acquisition, or other judicial or business activity involving the organization or its property must be reported to MOH officials within ninety days of the activity [42].

Merchandise Information:

- ✓ Amount of items uploaded.
- ✓ Sample size provided.
- ✓ List of contents (section) for the documents you uploaded.

Document's Information:

- ✓ A WHO-certificate of pharmaceuticals (COPP) that has been authorised by any mission in the GCC.
- ✓ A list of the device's attributes (SmPC).
- ✓ All safety data, such as a test procedure, a validating statement, etc., were kept in a distinct document specifically for the testing laboratory.
- ✓ Comprehensive explanation of Application Programming Interface (API) and diluents
- ✓ A summary of the previously owned automobiles and containers.
- ✓ A production method.
- ✓ Address and contact information of the Contract Research Organizations (CROs) participating (if any).
- ✓ Describe the outside backpack and any gear that was utilized.
- ✓ Material ratio (per unit mass or volume).
- ✓ Origin of the initial substance.
- ✓ Suggested title.
- ✓ Arabic/English brand patient data booklet.
- ✓ Pricing certification that has been verified either by nation of Activision's health departments.

Kuwait: Kuwait has laws governing the safety, potency, and quality of medicines as well as market regulation and intellectual property rights. Kuwait has maintained a legislative structure in place for 40 years and was a major player in the GCC. The primary governing agency that implements the governmental directive 302/80 for the registration of drug repurposing was the Kuwait Food and Drug Authority (KuFDA) [43].

"Kuwait was confronting an enormous legislative issue representing its remarkable progress of the regulating systems with available budgets potentially affecting consumers' prompt availability of medications," claims Dr. Reem Al-Essa, Director of a Registration Department of the Kuwait Pharmaceutical and Food Control.

Due to Kuwait's sparse population and lack of the necessary knowledge to create a strong foundation of production techniques for prescription medicines in the nation, the drug manufacturing ecosystem there was not particularly efficient. The Kuwait-Saudi Drug Industry Co., or Kuwait-Saudi Pharmaceutical Industries Company (KSPICO), was Kuwait's sole manufacturer. This business manufactures pharmaceutical drugs.

Comprehensive Data:

- Normative benchmark using CoA.
- Refined product illustration.
- Pamphlet providing health care (English and Arabic).
- Origin of inert components and API supplies.
- Details of the raw resources.
- With the aid of quality management, desired quality requirements.
- Information on stabilisation
- Three long batches (two pilot and one production).

- The very same 3 sets of enhanced trials were employed for lengthy research and lasted 6 months.
- Results of a bioavailability research.

Approvals:

- WHO-COPP.
- COA.
- A license stating that an item was Transmissible Spongiform Encephalopathy (TSE)-free.
- Official cost breakdown.
- Concentration of alcohol certification.
- Component diploma.
- Overview of nations in which a goods has a registration.

UAE:
Administration of Justice Data:

- Merchandise wholesaler in the UAE.
- Place of production.
- Legal representative and bearer of product registration.
- A producer of API.
- Legal standing.
- Cost summary.
- Announcement (in line with UAE Ministry of Health's Drug Enforcement Agency's laws on pharmaceuticals) [44]

Documentation:

- Data on pharmaceutical drugs.
- Packing, labelling, and health records leaflets.
- Aspect of preservation and storage stability.
- Content.
- Components made with animals.
- Details in a booklet.
- Pharmaceutical qualities.
- Information on generic drug bioavailability.

Each one of the 7 Government Regulators in the GCC has the following Institutional Framework, Roles, and Areas of Responsibility: Through direct contact with important regional regulatory agencies, the frameworks of the various GCC government regulators have been examined in **Table 4**.

The following were indeed the authorized initials of the GCC officials: Bahrain's Public Healthcare Protection Agency, Kuwait's State food and drug Control, Oman's Department Of public of Drug Matters and Drug Regulation, Qatar's Pharmaceuticals and Drug Regulation Dept, Saudi Arabia's State Food and Drug Agency, and the UAE's Enrollment and Drug Command Headquarters were just a few examples of organisations that regulate drugs. Five organisations were completely supported by the individual nations and operate independently of the Department of Health. Furthermore, Saudi Arabia was a separate, autonomous government that mostly receives money from application fee. The six GCC agencies oversee the regulation of pharmaceuticals intended for human consumption. Their primary areas of focus include approval to market, post-marketing monitoring, and quality assurance evaluation. Regardless of the size and benefits required for every supervisory agency, they also perform a number of other duties [45].

TABLE 4: GCC HAS THE FOLLOWING INSTITUTIONAL FRAMEWORK, ROLES, AND AREAS OF RESPONSIBILITY

Country	Bahrain	Kuwait	Oman	Qatar	Saudi Arabia	UAE
Name of authority	National Health Regulatory Authority	Kuwait Drug and Food Control	The General Directorate of Pharmacy and Drug Control	The Pharmacy and Drug Control Department	Saudi Food & Drug Authority	The Registration and Drug Control Department

Independent stand-alone authority		✓	✗	✗	✗	✓	✗
Budget/GBP		NA	2 million	NA	NA	85 million	1.6 million
Fees/GBP		9	230	130	None	>5,000	NA
Scope of registration responsibilities	Medicines for human use	✓	✓	✓	✓	✓	✓
	Veterinary medicines	✗	✓	✗	✗	✓	✓
	Medical devices and in vitro diagnostics	✓	✓	✓	✓	✓	✓
	Cosmetic products	✗	✓	✗	✗	✗	✗
	Food supplements	✗	✓	✗	✗	✗	✗
	Herbal medicines	✗	✓	✗	✗	✗	✗
Scope of activities	Marketing authorisation	✓	✓	✓	✓	✓	✓
	Post-marketing surveillance	✓	✓	✓	✓	✓	✓
	Sample analysis	✓	✓	✓	✓	✓	✓
	Advertising control	✗	✓	✓	✗	✓	✓
	Price regulation	✓	✓	✗	✓	✓	✓
	GMP inspection	✓	✓	✗	✗	✓	✗
	Clinical trial authorisation	✗	✗	✓	✗	✓	✓

CONCLUSION: There seems to be tremendous growth opportunity for India in the CIS. More than 90% of India's total bilateral trade with the CIS was with Belarus, Kazakhstan, Kyrgyzstan, Russia, Uzbekistan, and Ukraine, which were the key trading partners. To assess the diversity in document needs and registration procedures across different nations, research of both the legal provisions and procedure for a number of CIS nations has indeed been carried out. The lack of coordination between these countries might result in unnecessary duplication of effort and waste of precious resources, ultimately increasing medication lag. Harmonization makes it simpler and more efficient to enter multiple countries in a single goal. Companies can reduce the number of human and animal tests by just needing to produce one dataset for every region.

Reduced costs would also result from the development of regulatory papers for both new and generic medications. High-value medications for health were easily accessible to the general public. In order to harmonize technological and scientific standards, and in certain cases circumstances, the Member States, numerous Regional Harmonization Initiatives (RHIs) have been developed. These organizations were encouraged to suggest candidates to serve as permanent members of the Global Cooperative Group (GCG). Overall, Sales of pharmaceutical formulations climbed between Approximately USD 631.90 million in 2016-2017 to Approximately USD 788.27 million in 2018–2019. Future pharma supplies to the CIS nations have enormous potential.

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